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09/313,828 05/18/99 LAU

J 787444-2001

EXAMINER

020999

HM22/0406

FROMMER LAWRENCE & HAUG  
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NEW YORK NY 10151

ART UNIT NO. PAPER NUMBER

1615

DATE MAILED: 04/06/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ \_\_\_\_\_

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4 are pending in the application.

Of the above, claims 1-4, 6, 29, 31 & 37-41 are withdrawn from consideration.

- ☐ Claims \_\_\_\_\_ have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 5, 7-28, 30 & 32-36 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

Art Unit: 1615

### **DETAILED ACTION**

1. Applicant's election with traverse of Group II in Paper No. 11 is acknowledged. The traversal is on the ground(s) that it is reasonable to elect groups I and II. This is not found persuasive because Group I is a process and Group II is a product and the reasons for the restriction have already been set forth by the examiner and applicant provides no specific arguments to this restriction.

The requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 5, 7-28, 30 and 32-36.

#### *Claim Objections*

Claims 7-11 are objected to since they depend from non-elected claims. These claims are being examined since they are product claims, though dependent on the process claims.

#### *Claim Rejections - 35 U.S.C. § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 13-28, 30 and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: :1615

Referring to Fig. 2 in claim 13 is improper. Neither from the figure nor the brief description of the figure one can figure out what that compound is. The examiner suggests the naming of the chemical compound in the claim. It is unclear what applicant intends to convey by 'dissociating moiety' in this claim and other independent claims. These claims need restructuring because they are confusing.

Proper Markush format with the expression 'selected from the group consisting of' and the use of the terms either 'and' OR 'or' only before the last Markush member should be followed in claims 15, 32-33 and 36.

What is being conveyed by 'first member being soluble in second member comprising a liposome' in claim 18? What is the second member? Which is soluble in organic solvents? This claim is very confusing.

What is meant by soluble in liposome as recited in claim 22? Liposome is a bilayer structure and not a specific compound and this bilayer exists as a separate phase in water.

What is a target molecule as recited in claim 26 and 'polynuclear complex' as recited in claim 32?

*Claim Rejections - 35 U.S.C. § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Art Unit: 1615

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**5. Claims 5, 7-28, 30 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/00474 of record or Geho (4,603,044) also of record.**

**WO 88 and 044 both disclose liposomes containing either Cr, Co, Fe or Zn complexed with immunodiagnostic acid derivatives. The liposomes further contain either insulin or serotonin. (Note abstract, pages 9-16, 22-28 and claims; abstract, columns 2-22 and claims in 044).**

**6. Claims 5, 13, 22, 24, 32-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosworth (5,407,660) of record.**

**Bosworth discloses liposomes containing chelates of iron for diagnostic applications. The liposomes contain cholesterol (note the abstract, Examples and claims).**

**7. Claims 5, 13, 1518, 22, 24, and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldeschwieler (4,310,506) of record.**

**Baldeschwieler discloses liposomes containing chelates of metals such as Cr, In, Co, Zn with iminodiacetic acid for diagnostic applications. The liposomes contain distearoylphosphatidylcholine, dicetyl phosphate and cholesterol (note the abstract, columns 2-4, Examples and claims).**

Art Unit: :1615

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

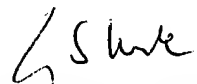
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Application/Control Number: 09/313,828

Page 6

Art Unit: :1615

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**

  
**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**April 4, 2001**